

BILLING CODE: 4410-09-P

DEPARTMENT OF JUSTICE Drug Enforcement Administration

[Docket No. 15-27]
Trinity Pharmacy I
Order Terminating Registration

On July 10, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Trinity Pharmacy I (hereinafter "Trinity I" or Respondent), which proposed the revocation of its DEA Certificate of Registration BT9848170, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 11130 Seminole Boulevard, Seminole, Florida. Administrative Law Judge Exhibit (ALJ Ex.) 1a, at 1. As grounds for the proposed action, the Show Cause Order alleged that Respondent's "continued registration is inconsistent with the public interest." *Id.* (citing 21 U.S.C. §§ 823(f) and 824(a)(4)). The Show Cause Order notified Respondent of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 15.

In a letter from its counsel dated August 12, 2015, Trinity I requested a hearing on the allegations. ALJ Ex. 2a. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ), who conducted a hearing on the allegations on January 4-8, 2016, in Arlington, Virginia, and on January 11-12, 2016, in Tampa, Florida. On May 12, 2016, the CALJ issued and served his Recommended Decision, which included the CALJ's recommendation that I revoke Respondent's registration and deny any pending applications for renewal. Recommended

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Decision (R.D.), at 66.¹ On June 2, 2016, the Government and Respondent each filed Exceptions to the CALJ's Recommended Decision. Thereafter, the record was forwarded to me for final agency action.

On March 22, 2017, during the course of reviewing the record, my office received a "Notice of Trinity Pharmacy I Change of Business Status" (hereinafter, "Notice") from the Government. In its Notice, the Government "informs the Acting Administrator of the change of business status for" Trinity I. Notice, at 1. Specifically, the Government states that, on March 17, 2017, counsel for Trinity I sent an email to the Group Supervisor of the Agency's Tampa, Florida District Office, which in turn attached a copy of a February 27, 2017 letter to the DEA's Registration Unit stating that Trinity I "desires to discontinue business activities" and enclosed "the original DEA Certificate of Registration for Cancellation." Feb. 27, 2017 Letter to DEA Registration Unit from Dale R. Sisco, Counsel for Trinity I, attached as Exhibit B to Notice, at 1. The Government attached to its Notice a copy of the email, the letter, and a copy of Trinity I's "original DEA Certificate of Registration" sent to the Agency. Notice at 1; Exhibits A-B to Notice. It is undisputed that Trinity I surrendered its "original DEA Certificate of Registration" to the Agency.

Based on these facts, I find that Respondent has surrendered its DEA registration certificate. Pursuant to 21 CFR § 1301.52(a), "the registration of any person . . . shall terminate, without any further action by the Administration, if and when such person . . . surrenders a

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¹ Trinity Pharmacy II ("Trinity II"), located in Clearwater, Florida, was served with a separate July 10, 2015 Order to Show Cause by the Government. ALJ Ex. 1b. Although the CALJ eventually ordered the consolidation of the evidentiary hearings for Trinity I and Trinity II, *see* ALJ Ex. 10 at 2, the CALJ wrote separate recommendations regarding each Respondent, and I therefore will issue a separate Order regarding the disposition of the Show Cause Order directed at Trinity II.

registration." As a result, I find that Respondent's registration terminated upon its surrender to the Agency, and accordingly, that the Show Cause proceeding is now moot.²

Pursuant to the authority vested in me under 5 U.S.C. § 554(e) and 28 CFR § 0.100(b), I declare that DEA Certificate of Registration BT9848170, issued to Trinity I, terminated upon its surrender to the Agency. Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a), as well as 28 CFR § 0.100(b), I further order that the Order to Show Cause issued to Trinity I be, and it hereby is, dismissed. This Order is effective immediately.

Dated: February 6, 2018.

Robert W. Patterson, Acting Administrator.

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In its Notice, the Government stated that it forwarded the February 27, 2017 correspondence from Trinity I's counsel for my consideration because it is "unsure of how Trinity 'disposed of' the 'controlled substances in the possession of the pharmacy,' when it disposed of them, and if applicable, to whom the controlled substances were provided." Notice at 2 (quoting Ex. B to Notice, at 1). This uncertainty, in turn, is based solely on the Government's observation that Trinity I's counsel cited to federal regulations in his letter that "do[] not exist." *Id.* Specifically, Trinity I's counsel stated that Trinity I "desires to discontinue business activities." Ex. B to Notice, at 1. As a result, he enclosed Trinity I's "original DEA Certificate of Registration" "as required by 21 C.F.R. Section 1307.14" and stated that Trinity I "does not possess any unexecuted Order forms," and "[a]ll controlled substances in the possession of the pharmacy have been disposed of in accordance with 21 C.F.R. Section 1307.21." *Id.*

The Government observed, correctly, that "21 C.F.R. Section 1307.14" and "21 C.F.R. Section 1307.21" "do[] not exist," and that the federal regulation setting forth the procedures a DEA registrant must follow when it desires to discontinue business activities altogether is 21 CFR § 1301.52(c). Notice, at 2. However, the Government failed to note that the provision cited by Trinity I's counsel related to the disposal of controlled substances (21 CFR § 1307.21) did exist until it was re-codified and amended on September 9, 2014 to what is now 21 CFR § 1301.52(c) and part 1317 of Title 21 of the Code of Federal Regulations. See generally Disposal of Controlled Substances Final Rule, 79 FR 53520 (Sept. 9, 2014). Most importantly, the Government offered no factual basis for why it is "unsure" of how Trinity I disposed of its controlled substances when Trinity I discontinued its business activities. Nevertheless, if the Government has a factual basis to believe that Trinity I violated the Controlled Substances Act when it disposed of its controlled substances as a result of its discontinued business activities, then I direct the Government to investigate such violations immediately.

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